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1	USPPI
2	Patient Information about
3	GARDASIL [®] (pronounced "gard-Ah-sill")
4	Generic name: [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine,
5	Recombinant]
6 7	Read this information with care before getting GARDASIL ¹ . You (the person getting GARDASIL) will need
8	3 doses of the vaccine. It is important to read this leaflet when you get each dose. This leaflet does not
9	take the place of talking with your health care provider about GARDASIL.
10	
11	What is GARDASIL?
12	GARDASIL is a vaccine (injection/shot) that is used for girls and women 9 through 26 years of age to help
13	protect against the following diseases caused by Human Papillomavirus (HPV):
14	Cervical cancer
15	Vulvar and vaginal cancers
16	Anal cancer
17	Genital warts
18	Precancerous cervical, vaginal, vulvar, and anal lesions
19	GARDASIL is used for boys and men 9 through 26 years of age to help protect against the following
20	 diseases caused by HPV: Anal cancer
21 22	
22	 Genital warts Precancerous anal lesions
23 24	• The diseases listed above have many causes, and GARDASIL only protects against diseases
25	caused by certain kinds of HPV (called Type 6, Type 11, Type 16, and Type 18). Most of the
26	time, these 4 types of HPV are responsible for the diseases listed above.
27	o GARDASIL cannot protect you from a disease that is caused by other types of HPV, other
28	viruses, or bacteria.
29	 GARDASIL does not treat HPV infection.
30	 You cannot get HPV or any of the above diseases from GARDASIL.
31 32	What important information about CARDASIL aboutd Lknow?
32 33	 What important information about GARDASIL should I know? You should continue to get routine cervical cancer screening.
34	 GARDASIL may not fully protect everyone who gets the vaccine.
35	 GARDASIL may not raily protect everyone who gets the vaccine. GARDASIL will not protect against HPV types that you already have.
36	
37	Who should not get GARDASIL?
38	You should not get GARDASIL if you have, or have had:
39	 an allergic reaction after getting a dose of GARDASIL.
40	• a severe allergic reaction to yeast, amorphous aluminum hydroxyphosphate sulfate, polysorbate
41	80.
42	
43	What should I tell my health care provider before getting GARDASIL?
44 45	Tell your health care provider if you:
45 46	 are pregnant or planning to get pregnant. GARDASIL is not recommended for use in pregnant women.
40 47	 have immune problems, like HIV infection, cancer, or you take medicines that affect your immune
48	system.
49	 have a fever over 100°F (37.8°C).
50	 had an allergic reaction to another dose of GARDASIL.
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GARDASIL®

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• take any medicines, even those you can buy over the counter.

Your health care provider will help decide if you should get the vaccine.

54 55 How is GARDASIL given?

56 GARDASIL is a shot that is usually given in the arm muscle. You will need 3 shots given on the following 57 schedule:

- Dose 1: at a date you and your health care provider choose.
 - Dose 2: 2 months after Dose 1.
 - Dose 3: 6 months after Dose 1.
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Fainting can happen after getting GARDASIL. Sometimes people who faint can fall and hurt themselves.
 For this reason, your health care provider may ask you to sit or lie down for 15 minutes after you get
 GARDASIL. Some people who faint might shake or become stiff. This may require evaluation or
 treatment by your health care provider.

67 Make sure that you get all 3 doses on time so that you get the best protection. If you miss a dose, talk to 68 your health care provider.

70 **Can other vaccines and medications be given at the same time as GARDASIL?**

GARDASIL can be given at the same time as RECOMBIVAX HB^{®1} [hepatitis B vaccine (recombinant)] or
 Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate
 Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine
 Adsorbed (Tdap)].

What are the possible side effects of GARDASIL?

The most common side effects with GARDASIL are:

- pain, swelling, itching, bruising, and redness at the injection site
- headache
- fever
- nausea
- dizziness
- vomiting
- fainting

There was no increase in side effects when GARDASIL was given at the same time as RECOMBIVAX HB [hepatitis B vaccine (recombinant)].

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91 There was more injection-site swelling at the injection site for GARDASIL when GARDASIL was given at
92 the same time as Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid
93 Conjugate Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis
94 Vaccine Adsorbed (Tdap)].

Tell your health care provider if you have any of the following problems because these may be signs of an allergic reaction:

- 98 difficulty breathing
- 99 wheezing (bronchospasm)
- 100 hives
- 101 rash
- 102

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- 103 Tell your health care provider if you have:
- swollen glands (neck, armpit, or groin)
- 105 joint pain
- 106 unusual tiredness, weakness, or confusion
- 107 chills
- generally feeling unwell
- 109 leg pain

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- shortness of breath
- chest pain
 - aching muscles
 - muscle weakness
 - seizure
 - bad stomach ache
 - bleeding or bruising more easily than normal
 - skin infection
- 119 Contact your health care provider right away if you get any symptoms that concern you, even several 120 months after getting the vaccine.
- 122 For a more complete list of side effects, ask your health care provider.
- 124 What are the ingredients in GARDASIL?
- The ingredients are proteins of HPV Types 6, 11, 16, and 18, amorphous aluminum hydroxyphosphate sulfate, yeast protein, sodium chloride, L-histidine, polysorbate 80, sodium borate, and water for injection.
- 128 This leaflet is a summary of information about GARDASIL. If you would like more information, please talk 129 to your health care provider or visit www.gardasil.com.
- 130
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- 133
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